UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,353	06/16/2005	Eric F Bernstein	BERN-0082	7199

26259 7590 04/03/2009

LICATA & TYRRELL P.C.
66 E. MAIN STREET
MARLTON, NJ 08053

EXAMINER	
PAGONAKIS, ANNA	
ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
04/03/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

Office Action Summary	Application No.	Applicant(s)	
	10/533,353	BERNSTEIN, ERIC F	
	Examiner	Art Unit	
	ANNA PAGONAKIS	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3 and 4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed 1/21/2009 has been received and entered into the present application.

Claims 1, 3-4 are pending. Accordingly, claim 1 has been amended and claims 2 and 5-7 have been cancelled.

Applicant's arguments, filed 1/21/2009 have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Priority

This claims benefit of PCT/US03/34250 filed 10/29/2003 and further claims benefit of provisional application 60/423,409 filed 10/31/2002.

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of PCT/US03/34250 filed 10/29/2003 and further claims benefit of provisional application 60/423,409 filed 10/31/2002, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The prior disclosures simply state that "the major histopathologic alteration of photoaged skin is the accumulation of histopathologic examination, has the staining characteristics of elastin and is thus, termed solar elastosis" (page 1). Though, it seems from Applicant's disclosure that photoaging and solar elastosis are

the same, Applicant's arguments 1/21/2009 seem to consider solar elastosis a sub-genus of photoaging. As such, Applicant has not disclosed a method of protecting humans exposed to sunlight against solar elastosis and photoaging comprising applying caffeine, theophylline or theobromine in an amount to protect the skin against solar elastosis.

It is noted that Applicant is not entitled to the priority date in these application for all claims in the instant claim set because the information contained within the previous referred filings does not support the granting of an earlier filing date. There is no instance, throughout the disclosure of a method of protecting and photoaging comprising applying caffeine, theophylline or theobromine in an amount to protect the skin against solar elastosis. **All claims are given a priority date of June 16, 2005.**

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, has possession of the claimed invention.

Present claim 1 is directed to a method of protecting humans exposed to sunlight against solar elastosis and photoaging comprising topically applying to skin of a human composition comprising caffeine, theophylline or theobromin in an amount effective to protect the skin against solar elastosis and photoaging.

In particular, the specification and claims as originally fail to provide adequate written description for the newly amended limitation directed to a method of protecting humans exposed to sunlight against

solar elastosis. Applicant has not provided any direction as to where the newly added limitation is found in the specification. Upon review of the instant disclosure, state that "the major histopathologic alteration of photoaged skin is the accumulation of histopathologic examination, has the staining characteristics of elastin and is thus, termed solar elastosis" (page 1). Though, it seems from Applicant's disclosure that photoaging and solar elastosis are the same, Applicant's arguments 1/21/2009 seem to consider solar elastosis a sub-genus of photoaging. As such, Applicant has not disclosed a method of protecting humans exposed to sunlight against solar elastosis and photoaging comprising applying caffeine, theophylline or theobromine in an amount to protect the skin against solar elastosis. It is clear therefore that Applicant was not in possession of protecting humans exposed to sunlight against solar elastosis in an amount effective to protect the skin against solar elastosis. While it is recognized that adequate written description of a limitation is not required to be stated *in haec verba* in the specification or claims as originally filed, adequate written support for all claim limitations must arise from either an explicit or an implicit suggestion by the disclosure to show that such a concept as now claimed was actually in possession of the Applicant at the time of the invention.

MPEP §2163 states, "The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test of sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed

subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983))...Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991)."

Accordingly, the claims are considered to lack sufficient written description and are properly rejected under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schroer (U.S. 3,957,994, provided by Applicant), as evidenced by Perricone (U.S. 5,409,693) in view of Baumgardner et al (U.S. 5,976,123).

Schroer teaches a composition comprising theophylline useful in the treatment of inflammation of the skin such as sunburn (abstract and column 2).

Perricone teaches a wide variety of skin diseases and skin conditions in which the skin has undergone some form of damage or accelerated aging can be traced, either directly or indirectly, to processes which either deplete or inhibit synthesis of collagen, and/or generate oxygen-containing free radicals, and/or oxidatively generate biologically active metabolites, generally via lipoxygenase pathways, which in turn either directly act upon the skin or mediate other processes which have adverse effect on the skin. Such is the case, for example, in radiation-induced skin damage, particularly ultraviolet radiation-induced skin damage (e.g., sunburn) where it appears possible that the transfer of energy from the radiation to the skin results in the generation of excited oxygen species, such as singlet oxygen, the superoxide anion, and hydroxyl radicals, that can damage lipid-rich membranes with the subsequent activation of the chemical mediators of inflammation and/or damage the skin cell membrane and DNA, and also where it appears that the radiation releases arachadonic acid which is then oxidized via two predominant pathways to produce either prostaglandins or leukotrines. Agents used for prevention and/or treatment of sunburn have been used prior to ultraviolet exposure in order to exert their protective effect (column 4, lines 60-64).

Thus given the teachings of Perricone, the very exposure to sunburn would have necessarily resulted in photoaging which meets Applicant's limitation directed to protection against photoaging.

Baumgardner et al teach that skin is subjected to long-term sun exposure exhibiting a variety of clinical changes which have been attributed to aging. The major histopathological finding in photoaging is the accumulation of material in the papillary dermis which has staining characteristics similar to elastin

and, therefore the condition is termed "solar elastosis." Solar elastosis replaces the normal collagen in the papillary dermis which results in the clinical changes observed in photoaged skin such as wrinkles. Increased collagen degradation occurs from UV exposure which has been shown to stimulate collagenase production by human fibroblasts and to upregulate collagenase gene expression (column 3, lines 40-52).

With regard to the treatment of solar elastosis, it would have been *prima facie* obvious to one of ordinary skill in the art to administer theophylline for the treatment of solar elastosis. One of ordinary skill in the art would be motivated to do so since solar elastosis occurs due to photoaged skin. Therefore, one of ordinary skill in the art would expect that treatment of photoaged skin would also mean the treatment of solar elastosis.

The schedule of administration and dosage amounts is well within the skill of the artisan at the time of the invention and would not be required undue experimentation or have been outside the realm of knowledge generally available to the skilled artisan. Factors that would have been taken into consideration when making such a determination would have included, but not have been limited to, the age, weight, sexy, diet and medical condition of the patient, severity of the disease, route of administration, pharmacological considerations, e.g., activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination. Thus, the schedule of administration, in this case administration prior to exposure, would have been in the purview of one skilled in the art.

Conclusion

No claim is found to be allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNA PAGONAKIS whose telephone number is (571)270-3505. The examiner can normally be reached on Monday thru Thursday, 9am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AP

/Patricia A. Duffy/

Primary Examiner, Art Unit 1645